



UNITED STATES PATENT AND TRADEMARK OFFICE

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United States Patent and Trademark Office  
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Elizabeth W. Mata  
Hamilton, Brook, Smith & Reynolds, P.C.  
530 Virginia Road  
P.O. Box 9133  
Concord, MA 01742-9133

In Re: Patent Term Extension  
Application for  
U.S. Patent No. 5,218,108

MAILED  
JUN -7 2012  
OPLA

Dear Ms. Mata:

An interim extension under 35 U.S.C. § 156(e)(2) is enclosed extending the term of U.S. Patent No. 5,218,108 for a period of one year. While a courtesy copy of this letter is being forwarded to the Food and Drug Administration (FDA), you should directly correspond with the FDA regarding any required changes to the patent expiration dates set forth in the Patent and Exclusivity Data Appendix of the Orange Book (Approved Drug Products with Therapeutic Equivalence Evaluations) or in the Patent Information set forth in the Green Book (FDA Approved Animal Drug Products). Effective August 18, 2003, patent submissions for publication in the Orange Book and Docket \*95S-0117 need to be submitted on form FDA-3542 which may be downloaded from FDA's Electronic Forms Download Website:

<http://www.fda.gov/opacom/morechoices/fdaforms/default.html>  
(<http://www.fda.gov/opacom/morechoices/fdaforms/FDA-3542.pdf>).

Inquiries regarding this communication should be directed to Raul Tamayo by telephone at (571) 272-7728, or by e-mail at [raul.tamayo@uspto.gov](mailto:raul.tamayo@uspto.gov).

Mary C. Till  
Senior Legal Advisor  
Office of Patent Legal Administration  
Office of the Deputy Commissioner  
for Patent Examination Policy

cc: Office of Regulatory Policy  
Food and Drug Administration  
10903 New Hampshire Ave., Bldg. 51, Rm. 6222  
Silver Spring, MD 20993-0002

RE: VOLUVEN® (6%  
hydroxyethyl starch 130/0.4 in 0.9%  
sodium chloride injection  
Docket No.: FDA-

Attention: Beverly Friedman

UNITED STATES PATENT AND TRADEMARK OFFICE

In re Fresenius Kabi Deutschland GmbH :  
Request for Patent Term Extension : ORDER GRANTING  
U.S. Patent No. 5,218,108 : INTERIM EXTENSION

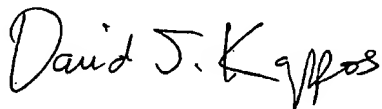
Fresenius Kabi Deutschland GmbH, the owner of record in the United States Patent and Trademark Office (USPTO) of U.S. Patent No. 5,218,108, filed an application for patent term extension under 35 U.S.C. § 156 on February 21, 2008. The extended term of the patent is due to expire on June 8, 2012. The patent claims the active ingredient 6% hydroxyethyl starch 130/0.4 in 0.9% sodium chloride injection in the human drug product VOLUVEN®, which was approved by the Food and Drug Administration for commercial marketing or use on December 27, 2007. An extension of 1,371 days is requested.

The initial USPTO review of the application to date indicates that the subject patent is eligible for extension of the patent term under 35 U.S.C. § 156. A final determination of the length of the extension of the patent term and issuance of a patent term extension certificate cannot be made until a final determination of the length of the regulatory review period is made. Because the extended term of the patent would expire before a certificate of patent term extension can be issued, an interim extension of the patent term is appropriate.

An interim extension under 35 U.S.C. § 156(e)(2) of the term of U.S. Patent No. 5,218,108 is granted for a period of one year from the extended expiration date of the patent.

June 7, 2012

Date



David J. Kappos  
Under Secretary of Commerce for Intellectual Property and  
Director of the United States Patent and Trademark Office